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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,588	06/01/2001	Hitoshi Fukushima	04783-026002	9233

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EXAMINER
TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/26/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/870,588	Applicant(s) FUKUSHIMA ET AL.	
	Examiner My-Chau T. Tran	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12,14,15 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12,14,15 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *01 April 2003* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/09/03 has been entered.

2. Applicant's amendment filed 4/17/03 in Paper No. 12 is acknowledged and entered. Claim 11 is amended by the amendment.

3. Claims 11-12, 14-15, and 17 are pending.

Drawings

4. The drawings were received on 4/17/03. These drawings are acceptable.

5. Claims 11-12, 14-15, and 17 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11-12, 14-15, and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claims 11 and 15 briefly recites a device comprises electrodes and transducing elements. The electrodes of claim 11 comprise of a molecule recognizing film formed on the electrodes. The electrodes of claim 15 comprise of the molecule recognizing film formed between electrodes.

The specification disclosure does not sufficiently teach a device that comprises the combination of the molecule recognizing film formed ***on and between*** the electrodes or a device that comprises of the molecule recognizing film formed ***only*** between electrodes.

The specification description is directed to a device that comprises a molecule recognizing film formed on the electrodes (see pg. 4, lines 14-17; pg. 6, lines 26-27). This device clearly does not provide an adequate representation regarding a device that comprises the combination of the molecule recognizing film formed ***on and between*** the electrodes or a device that comprises of the molecule recognizing film formed ***only*** between electrodes. The specification does not teach a device that comprises the combination of the molecule recognizing film formed ***on and between*** the electrodes or a device that comprises of the molecule recognizing film formed ***only*** between electrodes.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of a device that comprises a molecule recognizing film formed on the electrodes disclosed by the specification, the skilled artisan cannot envision a device that comprises the combination of the molecule recognizing film formed ***on and between*** the electrodes. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the claimed device that comprises the combination of the molecule recognizing film formed ***on and between*** the electrodes. The specification does not teach the device that comprises the combination of the molecule recognizing film formed ***on and between*** the electrodes or a device that comprises of the molecule recognizing film formed ***only*** between electrodes. Therefore, only the device a molecule recognizing film formed on the electrodes., but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 11-12, 14-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US Patent 5,200,051).

Cozzette et al. disclose a sensor device (biosensor) that comprises an electrode, transducer (transducing element) and a semipermeable film (molecule recognizing film), which is a polymer (Abstract; col. 14, line 20-25; col. 19, lines 31-35). The electrode would produce a signal from the film (col. 12, line 30-37; col. 19, line 31-39). The organic film is printed (dispensed) onto the electrode (col. 15, line 40-42; col. 26, 36-55). "An important aspect of the microfabricating process described in the present invention is an automated system which is able to microdispense precise and programmable amounts of the materials" (col. 58, lines 44-67)

(refers to claims 12 and 14). Cozzette et al. also disclose the biosensor comprises a planar wafer on which a first structure comprising a base senor (col. 12, lines 27-37). Additional structures are then established over the resulting base sensor, which include a semipermeable film or permselective layer. One such permselective layer is the support matrices that possess the physical and chemical features necessary to support the various bioactive molecules that constitute the principal means for converting the particular analytes in a given analytical sample into detectable and/or quantitatively measurable species (col. 12, lines 45-51; col. 14, lines 35-39). Additionally, the location of the molecule recognizing film (e.g. on and/or between the electrodes) would be a choice as experimental design and is considered within the purview of the prior art. Therefore, Cozzette et al. device include all of the required elements of the device of the presently claimed invention.

10. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Ribi et al. (US Patent 5,491,097).

Ribi et al. disclose a bioelectronic sensor device (col. 2, lines 53-67). The bioelectronic sensor device comprising an electrically insulating solid support, a highly oriented polymerized film (molecule recognizing film) that is electrically semiconducting, and distal from the support is a member of a specific binding pair joined to the film (col. 3, lines 15-22; fig. 3 and 5). The electrodes are formed on the non-conducting substrate followed by the coating with the electrically conducting polymer (col. 9, lines 60-67). The electrodes are connected through external leads (transducing element) (col. 24, lines 40-43; fig. 5). "The member of a specific binding pair joined to the surfactant molecules, wherein the specific binding pair member is used

for linking to a molecule. The molecule relays a change in the electromagnetic, e.g., electrical or optical properties of the polymer, when such molecule is bound, either directly or indirectly, to the surfactant bound specific binding member. In addition, electrode arrays are provided, which are insulated from the sample medium while in electrical conducting relationship with the polymeric layer" (col. 3, lines 19-28). Therefore, the device of Ribi et al. anticipates the presently claimed invention.

11. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al. (US Patent 5,605,662).

Heller et al. disclose an electronic sensor device (abstract). The device includes a microelectrode, electrode circuit board (transducing element), and the permeation layer (molecule recognizing film) (col. 9, line 18-20; col. 5, lines 42-44). The permeation layer allows for diffusion to occur of molecules such as solvent, counter ions, and electrolysis gases (col. 13, lines 29-53). The transducing element (electrode) would produce a signal from the film (col. 9, line 61-67; col. 10, line 31-43). The microloaction can be any shape such as round (col. 10, lines 16-17). Therefore, the device of Heller et al. anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 11-12, 14-15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (US Patent 5,605,662) and Johnson (US Patent 4,216,245).

Heller et al. disclose an electronic sensor device (abstract). The device includes a microelectrode (electrodes) and the permeation layer (organic film) (col. 9, line 18-20). The permeation layer allows for diffusion to occur of molecules such as solvent, counter ions, and electrolysis gases (col. 13, lines 29-53). The transducing element (electrode) would produce a signal from the film (col. 9, line 61-67; col. 10, line 31-43). The microloaction can be any shape such as round (col. 10, lines 16-17).

Heller et al. differs from the claimed invention in failing to specifically teach that the organic film is printed onto the surface of the electrode, which form dot.

Johnson teaches a technique of printing the organic thin film (reagent) on an electrode (matrix) in microdot format (col. 2, line 13-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Heller et al. by including the technique of printing the organic thin film onto the electrode as taught by Johnson for the well known advantage of providing a rapid method of applying the organic film to the electrode in a manner which prevents interaction.

Withdrawn Rejections

14. The previous rejections 35 USC 112, first paragraph (new matter), for claims 11-12, 14-15, and 17 have been withdrawn in view of applicant's argument that "[t]he claimed molecule recognizing film is supported on pg. 8, lines 23-27. Moreover, support can be found in the

disclosure at page 12, line 12 to page 13, line 2. As such, Applicants respectfully assert that, "the molecule recognizing film adsorbing aromatic molecules to change an electric resistance in connection with a change in volume of the molecule recognizing film by absorbing aromatic molecules inside the molecule recognizing film" as claimed in claim 11 is fully supported in the specification as filed."

15. The previous rejections under 35 USC 103(a) as being obvious over Cozzette et al. (US Patent 5,200,051) for claims 12, 14-15, and 17 have been withdrawn in view of applicant's amendments of claim 11.

Response to Arguments

16. Applicant's argument(s) directed to the rejection under 35 USC 102(b) as being anticipated by Cozzette et al. (US Patent 5,200,051) for claim 11 was considered but they are not persuasive for the following reasons.

Applicant contends that Cozzette does not anticipate the presently claimed device because the presently claimed device "[c]all for a molecule recognizing film that absorbs aromatic molecules to change an electrical resistance in connection with a change in volume of the molecule recognizing film by absorbing the aromatic molecules inside the molecule recognizing film."

Applicant's arguments are not convincing since Cozzette et al. teaches all the **structural** limitation of the presently claimed device. The presently claimed device comprise of electrode, a molecule recognizing film, and a transducing elements. The device of Cozzette et al. discloses a sensor device (biosensor) that comprises an electrode, transducer (transducing element) and a

semipermeable film (molecule recognizing film). Thus, the device of Cozzette et al. teaches all the **structural** limitation of the presently claimed device. The limitation wherein the "*molecule recognizing film absorbs aromatic molecules to change an electrical resistance in connection with a change in volume of the molecule recognizing film by absorbing the aromatic molecules inside the molecule recognizing film*" is consider a functional limitation of the device. Applicant is direct to the MPEP 2114 that recite:

>While features of an apparatus may be recited either structurally or functionally, claims< directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re* Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

That is the manner or method in which the "molecule recognizing film" is to be utilized is not germane to the issue of patentability of the device itself. Therefore the device Cozzette et al. anticipate the presently claimed device because Cozzette et al. teaches all the structural limitations of the presently claimed device, which are a molecule recognizing film and a transducing elements.

17. Applicant's argument(s) directed to the rejection under 35 USC 103(a) as being unpatentable over Heller et al. (US Patent 5,605,662) in view of Johnson (US Patent 4,216,245) for claims 11-12, 14-15, and 17 was considered but they are not persuasive for the following reasons.

Applicant alleges that "[H]eller is completely silent with respect to changing an electrical resistance of a molecule recognizing film and, furthermore, with respect to a change in volume

of the molecule recognizing film." Therefore the proposed combination of Heller and Johnson does not yield the presently claimed device.

Applicant's arguments are not convincing since Heller et al. teaches all the **structural** limitation of the presently claimed device. The presently claimed device comprise of electrode, a molecule recognizing film, and a transducing elements. The device of Heller et al. discloses an electronic sensor device (biosensor) that comprises microelectrode, electrode circuit board (transducing element), and the permeation layer (molecule recognizing film). Thus, the device of Heller et al. teaches all the **structural** limitation of the presently claimed device. The limitation wherein the "*molecule recognizing film absorbs aromatic molecules to change an electrical resistance in connection with a change in volume of the molecule recognizing film by absorbing the aromatic molecules inside the molecule recognizing film*" is consider a functional limitation of the device. Applicant is direct to the MPEP 2114 that recite:

>While features of an apparatus may be recited either structurally or functionally, claims< directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re* Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

That is the manner or method in which the "molecule recognizing film" is to be utilized is not germane to the issue of patentability of the device itself. Therefore the device Heller et al. anticipate the presently claimed device because Heller et al. teaches all the structural limitations of the presently claimed device, which are a molecule recognizing film and a transducing elements. The combination of Heller et al. and Johnson would teach the presently claimed device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
August 23, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER